

510(k) SUMMARY**SpineWorks, LLC – Anterior Lumbar Device (ALD)****APR 11 2014**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness SpineWorks' ALD.

A. SUBMITTERS INFORMATION

Submitter Name: BioVera, LLC.
Submitter Address: 815 Iris Lane, Vero Beach, FL 32963
Contact Person: Robert A Poggie, PhD
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Date of Submission: January 20, 2014

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name: SpineWorks, LLC
Manufacturer Address: 2802 Florida Street
Huntington Beach, CA 92647, USA
Registration Number: 3005471884
Contact Name: Doug Neary
Title: President
Device Trade Name: SpineWorks Anterior Lumbar Device
Device Common Name: Intervertebral body fusion device
Classification Name: Intervertebral body fusion device - lumbar
Classification Code: MAX – Class II
Classification Panel: Orthopedic
Regulation Number: 21 CFR section 888.3080

C. PREDICATE DEVICES

K111166 SpineWorks A-Wedge Anterior Interbody System; manufactured by SpineWorks, LLC
K121693 A-Wedge Anterior Interbody System manufactured by Sapphire Medical Group, LLC
K123969 The XIPHOS™ ALIF manufactured by Diffusion Technologies

D. DEVICE DESCRIPTION

The SpineWorks Anterior Lumbar Device (SW ALD) was developed for the stabilization of the lumbar spinal column. The body of the device is a rounded-trapezoidal shape with two large windows allowing placement of bone graft and facilitating fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. SW ALD implants are available in two lordotic configurations (6° and 11°) of various heights and widths to restore lumbar lordosis and the associated sagittal balance. SW ALD implants have three tantalum x-ray markers. The SW ALD device is single-use only.

Materials: Medical grade PEEK (ASTM F2026) machined from Vestakeep i4R extruded bar stock (Evonik Polymers Technologies GmbH, FDA master file MAF #1922). Medical grade tantalum (ASTM F560-08) was used to fabricate the radio opaque markers.

Function: SW ALD devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion.

E. INTENDED USE

The SpineWorks Anterior Lumbar Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). SW ALD Interbody System implants are to be used with autogenous bone graft and implanted via an anterior, lateral or anterolateral approach. SW ALD Interbody System implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Subject SW ALD devices are machined from medical grade extruded PEEK bar stock and fitted with radio opaque markers made from tantalum for visualization in radiography. The PEEK and tantalum materials are intended for permanent implantation. SW ALD devices are designed to fit the anatomic profile of the lumbar spine. Two lordosis-angle options are offered; 6 and 11 degrees. Height options range from 10 to 18mm, in 2 mm increments. One depth option is offered, 24 mm, and four width options of 26, 30, 38, and 44 mm.

The technological characteristics of SpineWorks ALD devices are identical to the cited predicated device excepting a change in the extruded PEEK bar stock that is used to machine the subject devices and addition of two width options of 38 and 44mm. The design, instruments, sterilization, labeling, intended use, two of four width options, and machining processes are identical for the subject device and the cited predicate devices. The change in material is as follows: the subject SW ALD devices are machined from Evonik Vestakeep i-Grade stock shapes, and the predicate A-Wedge AIS devices are machined from Orthoplastics Ltd. Vertepeek extruded bar and the predicate SpineWork's A-Wedge A.I.S. devices are machined from Invibio PEEK-OPTIMA extruded bar. The predicate device, K123969, is machined from the identical Evonik i4R PEEK bar stock as the subject SW ALD device, and is similarly indicated for lumbar spinal fusion.

Mechanical testing per the FDA Guidance Document for spinal devices and the information contained in Evonik's master file MAF # 1922 show the change in materials for the subject SW ALD devices and predicates Sapphire Medical Group's A-Wedge AIS and SpineWork's A-Wedge A.I.S. devices do not raise new types of safety and efficacy issues; therefore the subject and predicate devices are substantially equivalent.

G. PERFORMANCE DATA

Characterization of SW ALD devices was performed per the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" issued on June 12, 2007. Mechanical testing of the devices was performed per modified version of ASTM standard F2077-03 for static compression and dynamic compression. Also, ASTM F2267-04 was performed to evaluate subsidence. All static and dynamic test results met or exceeded the requirements for intervertebral body fusion devices intended for use in the lumbar spine.

H. CONCLUSION

The SW ALD Interbody System is substantially equivalent to the predicate devices in terms of indications for use, design, materials, performance, and function.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SpineWorks, LLC
% Robert A. Poggie, Ph.D.
BioVera, LLC
815 Iris Lane
Vero Beach, Florida 32963

April 11, 2014

Re: K133340

Trade/Device Name: SpineWorks Anterior Lumbar Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 20, 2014
Received: January 23, 2014

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133340

Device Name
SpineWorks Anterior Lumbar Device

Indications for Use (Describe)

The SpineWorks Anterior Lumbar Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). SpineWorks Anterior Lumbar Devices are to be used with autogenous bone graft and implanted via an anterior, lateral or anterolateral approach. SpineWorks Anterior Lumbar Devices are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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